Exhibit 18

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Gary D. Ginsberg, Esquire Gingsberg & O'Connor, P.C. 300 Atrium Way, Suite 100 Mount Laurel, New Jersey 08054

Re: Ruggierio v. Yamaha Motor Corporation, USA

Dear Mr. Ginsberg,

The following report is preliminary and based on information available to date. The issues described below are subject to change as additional information becomes available.

Product Safety Management

Product safety management is a system that a reasonably prudent manufacturer puts in place <u>before</u> the first product is conceived to ensure that the final product, along with its warnings, packaging and marketing materials, is reasonably safe. It starts with a statement of commitment for product safety from top management and develops a company's procedures to <u>identify hazards</u>, <u>assess the risk</u>, <u>apply adequate safety measures to eliminate hazards</u> from the design, places a <u>guard between users and potential injury</u> and to <u>warn users of all hazards</u> that have not been eliminated or

adequately guarded through technically feasible and economically practical safety measures.

Product safety management theory has been published and reviewed by scholars in the field for over 50 years. As can be shown from the wide dissemination and acceptance by academia, business and legal professionals, these concepts are widely used and accepted throughout the safety community.

Safety management is primarily a tool to protect consumers before they purchase products. When used correctly, these principles are a reasonable model for injury prevention. It is only after an injury that they are applied to determine if the managers failed to apply the accepted principles.

When evaluating a company's product safety management program, it is incumbent upon a reasonably prudent manufacturer to apply the following accepted safety principles to ensure that the products are reasonably safe.

- 1. <u>Establish and observe a written safety policy</u>. This policy should emphasize commitment to safety. In writing, it will insure all employees obtain clear guidance on safety issues. The policy should set forth a method for discussing safety responsibilities.
- 2. Adequately identify and evaluate product hazards. A hazard is the inherent capability of a product to do harm. Manufacturers, distributors, and retailers must review the potential injury-causing energy and evaluate severity and foreseeability.
- 3. Perform an adequate risk assessment integrating product hazards, the environment, and foreseeable consumer use. Once hazards are identified, the reasonably prudent manufacturer/distributor/retailer must consider the conditions of use under which the injury-causing mechanism (hazard) can cause harm to the user.

Analysis of the environment where the product will foreseeably be used, especially in light of product promotion, is critical in discerning how the consumer may foreseeably use the product, even if it is not the use intended by the manufacturer.

The product must be reasonably safe prior to distribution in commerce. If it is not possible to eliminate the hazard, the reasonably prudent manufacturer, distributor, and retailer must take steps to guard against the hazard, to adequately inform users of the danger inherent in the product, and to motivate them to avoid that danger.

- 4. <u>Monitor the safety performance of the product after sale and use, and take corrective action where necessary</u>. Once products are distributed to consumers, a responsible manufacturer/distributor/retailer must determine where injuries can occur, or if a product defect (including lack of adequate labeling and safety information) could create injuries. Where corrective action is needed to substantially reduce or eliminate injuries, consumer notification and additional corrective measures must be implemented to insure consumer safety.
- 5. <u>Develop adequate warnings and training to motivate consumers to understand and avoid dangers</u>. This is critical and relatively inexpensive. When consumers have sufficient data to make an informed decision about safety, they are in a better position to address safety issues.

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A key precept of safety management concerns products with inherent capability to do catastrophic harm. In priority order, the duty of a reasonably prudent manufacturer is to <u>eliminate the hazard</u>, or, if this is not possible while preserving utility, <u>guard against the hazard</u>. At a minimum, the manufacturer must properly <u>inform users of the danger inherent</u> in the product and motivate them to avoid injury.

The first concept is the safety engineering hierarchy of priorities:

- Eliminate hazards
- When hazards cannot be eliminated, provide feasible safeguards against them
- Provide warnings and personal protective equipment against remaining hazards

National Safety Council
Product Safety Management Guidelines, 1989

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In 1931, H. W. Heinrich, Assistant Superintendent for the Engineering and Inspection Division of the Travelers Insurance Company published the primary modern text of Safety Management, *Industrial Accident Prevention, A Scientific Approach*. The results of his in-depth analysis of more than 5000 accidents revealed four fundamental principles of scientific accident prevention:

- 1. Executive interest and support
- 2. Cause-analysis
- 3. Selection and application of remedy
- 4. Executive enforcement of corrective practice

These concepts, developed by Heinrich for the Joliet Steel Works, have evolved into modern day safety management practices. Scholarly research has further developed the foundation for safety management practices.

The Consumer Product Safety Commission incorporated these principles in its 1975 publication, updated in 2006, *Handbook and Standard for Manufacturing Safer Consumer Products*. The Commission addressed executive action, design review, distribution and corrective action.

In 1983, Harold Roland of the University of Southern California Institute of Safety and Systems Management and Brian Moriarty authored *System Safety Engineering and Management*, outlining the need for product safety policy and analysis to prevent injuries. They evaluated hazard identification, severity and a systematic approach to identify defects.

The National Safety Council first published *Product Safety Management Guidelines* in 1989 describing the relationship between marketing, manufacturing, and safety communications as a key to corporate accident prevention. Their analysis includes the hierarchy of safety management and prevention programs to substantially reduce or eliminate injuries.

Background

I am a Board Certified Product Safety Manager and Hazard Control Manager. I hold an Executive Certificate in Safety Management from the American Society of Safety Engineers, and I am a member of the Human Factors and Ergonomics Society. I hold a Certificate in Risk Communication from the Harvard School of Public Health. For the past 30 years, I have provided risk assessment and product safety management services to attorneys, corporations and government organizations.

From 1974 to 1981, I worked at the U.S. Consumer Product Safety Commission (CPSC), part of which time I served as Legal Advisor to the Director, Office of Product Defect Identification, and was responsible for identifying products which contained a defect which could create a substantial product hazard, developing voluntary

corrective action plans under Section 15 of the Consumer Product Safety Act including the recall of substantially hazardous consumer products, and notification to the public of the danger through warnings and other media. (See attached Curriculum Vitae).

As CPSC Program Manager for Sports, Recreation and Power Equipment (1977-1980), I supervised a team of engineers, epidemiologists, human factors specialists, and technical communication staff in the evaluation of injury statistics, engineering data, and product use information to achieve a reduction in consumer products injuries. Injury prevention tools combined mandatory and voluntary standards, on-product warnings, and safety education campaigns resulting in publication of the Federal Safety Standard for Walk-Behind Power Lawn Mowers 16 CFR 1205 (1979). I served as Commission representative to various industry groups and standards development committees, including American National Standards Institute (ANSI), American Society for Testing & Materials (ASTM), the Outdoor Power Equipment Institute and the Sporting Goods Manufacturers Association.

I have been retained as a consultant for a number of major manufacturers, including the *Toro Company* on product safety issues, the *Vendo Company* for developing warning labels and safety bulletins, the *Jensen Corporation* for warnings and safe operation of industrial equipment, *Nobel Chemical Company* for adequacy of warnings, *Corning Glass* for evaluation of recalls, *BernzOmatic*, a division of the Newell Group, for development of point-of purchase recall displays, warnings, and advertising, *Arctic Cat*, *Inc*. for analysis of all-terrain vehicle off-road safety, including owner's manuals, instructions, warnings and foreseeable use, and *Visioneer*, Inc. in developing a program to upgrade computer scanners. I have developed a program for *Global Industries* to improve executive chair stability, reviewed warnings on heavy equipment for *Daewoo Heavy Industries America*, investigated safety issues for Carson Industries, Inc. and assisted *CISCO Systems* in recall development. I have designed a warning label for *Whisper Communications, Inc.*, and assisted *Wham-O, Inc.* in recall procedures. I have provided risk analysis, recall assistance and consumer warnings and instructions to Restoration *Hardware, Inc.*, have developed warnings for *Plastics Research Corp*.

concerning use of decorative building materials as protective barriers. I have reviewed advertising and promotional material for *ACH Foods* and assisted *Hilton Hotels* on recall issues. I have advised *Swimways Corporation* on product safety management and warnings. I have advised *AsiaEXP* on risk assessment, labeling and product standards and have assisted *Dick's Sporting Goods* in developing safety communications and warnings. I served as Product Safety Coordinator for compliance with a Department of Justice/CPSC Consent Agreement and Order for *LM Imports*. For *Rollz International* (Netherlands), I revised the user manual for American and Canadian markets. I provided research and analysis on ATV safety for the National Association of Attorneys General and served as the Chairman of the *Florida Consumer's Council* (1993-2007).

I have developed on-product warnings and instructions for a number of manufacturers and distributors. A few examples include:

- <u>Vendo Company</u> for vending machine warnings
- <u>Arctic Cat, Inc.</u> for ATV's
- Whisper Communications for electrocution hazards
- <u>Plastics Research Corp.</u> for building material warnings
- <u>Daewoo Heavy Industries America</u> for labeling of heavy machinery
- <u>Swimways Corporation</u> for warnings on children's pool products
- <u>Dick's Sporting Goods</u> for fitness equipment

I have lectured at the National Safety Council Annual Congress and Exposition on the following topics:

• When Risk Can't Be Eliminated: <u>Building Adequate Warnings</u>, Los Angeles, California, 1998

- <u>Injury Prevention Analysis</u>: Guidelines for Product Safety Managers, Chicago, Illinois, 1997
- Post Sale Corrective Action Plans <u>Recalls and Consumer Notice</u>,
 Orlando, Florida, 1996

I have also addressed industry groups on warnings issues for the International Consumer Product Health and Safety Organization and the CPSC.

In 1991, I wrote an article for Professional Safety, the Journal of the American Society of Safety Engineers (ASSE), entitled *Safety Management and the Consumer Product Safety Commission*. Reviewed and accepted by the ASSE editorial board, the section on warnings reads in part:

VI. Warn users of product dangers and motivate them to avoid injury.

In addition to hazard elimination, product warnings and instructions must help the user avoid dangers, including those that remain after thorough attempts to eliminate or guard. An explicit warning that includes a signal word, statement of the hazard, appropriate behavior and description of the danger's consequences is required. A pictogram illustrating consequences often helps communicate the danger, especially to those who cannot read.

I have written a chapter in <u>Children and Injuries</u>, entitled *Standards*, Regulations and Safety Guidelines to Protect Children from Injury.

Incident Facts

On June 30, 2012 Thomas Fimple was operating his 2009 Yamaha FZR Waverunner in Atlantic County, New Jersey with his girlfriend, Angela Ruggierio as a passenger. Near the Brigantine Bridge, Thomas accelerated and Angela, wearing a bathing suit, fell backward off the Waverunner. The powerful thrust from the jet nozzle lacerated her rectum and damaged her intestines. Mr. Fimple, a longtime personal watercraft (PWC) rider, acknowledged he had not read the instructions or labeling. With many years of experience, he felt he was thoroughly familiar with the operation of the Waverunner. Angela, boarding from the side as described in the owner's manual, did not see any warnings on the front, as they were blocked by Mr. Fimple sitting on the Waverunner, or on the back, not within view of her side mount.

Opinions

The opinions contained herein are stated within a reasonable degree of safety management certainty.

- 1. Yamaha failed to act as a reasonably prudent distributor of personal watercraft to adequately protect passengers from the potentially catastrophic risks of injury associated with the foreseeable use of 2009 Yamaha FRZ Waverunner.
- 2. Yamaha failed to perform a risk assessment to adequately integrate product hazards, the environment and foreseeable consumer use, and failed to take adequate corrective action to substantially reduce or eliminate injury.
- 3. Yamaha failed to adequately warn passengers of the dangers of severe rectal and vaginal injuries directly associated with the water jet propulsion system used to power the Waverunner. The general warning under the handlebars was not sufficient to

warn passengers of the danger and the rear label failed to provide a prominent and conspicuous warning.

- 4. Yamaha failed to adequately warn riders that protective clothing was required to protect passengers from the devastating injuries caused by the jet thrust. Yamaha failed to adequately inform passengers of the need for and availability of non-wetsuit protection to substantially reduce or eliminate injury, especially where the engine fails to shut down and a passenger falls backwards off the Waverunner.
- 5. Yamaha failed to adequately warn Waverunner passengers of the devastating and potentially catastrophic injuries associated with the foreseeable use of the 2009 FRZ Waverunner. On-product labels were not adequately readable, accessible or within reasonable view of the intended user to alert them to the danger of rectal or intestinal injuries. The label on the Waverunner is not placed where it is in view of the passenger and is not reasonable to substantially reduce or eliminate injury.
- 6. Yamaha failed to adequately warn operators of the 2009 FRZ Waverunner of the devastating and potentially catastrophic injuries to passengers associated with the foreseeable use of the Waverunner. The label under the handlebars is not adequately readable, or accessible to the intended user and the label does not conform to the 2007 ANSI Z535.4 industry voluntary Standard for Product Safety Signs and Labels.

Chronology

As early as 1991, the Journal of Obstetrics and Gynecology published by scientific publisher Elsevier (Pub Med 1923248) an article entitled Vaginal Laceration following a Jet-Ski Accident. The article indicated:

- Vaginal injuries are not uncommon in women who use jet skis.
- Tears are the most common injuries.
- In severe cases, water may force its way into the abdomen.

In 1999, the Journal of Diseases of the Colon and Rectum published an article entitled Rectal Injury caused by a Personal Watercraft Accident. They stated "A high suspicion of rectal injury must be maintained in victims who have fallen from the back of a personal watercraft."

In November of 1999, the major distributors of personal watercraft funded a study entitled <u>Development and Evaluation of Labeling for Personal Watercraft (PWC)</u>. They hired Applied Safety and Ergonomics Inc. of Ann Arbor, Michigan, to provide analysis and a research report and the development of on-product labels on behalf of Yamaha and the other producers and distributors. Paul Frantz, among others, was a principal author of the study.

The report states that "water injection" injuries did not show up in the accident data but industry knowledge and the medical literature identified the potential for rectal and vaginal injuries from "falls in the water." The report states that previous studies had indicated that wearing a wetsuit would protect the passenger, but they acknowledge that some users would not be willing to wear a wetsuit and ultimately decided that including "equivalent protection" on the label would be acceptable.

As part of the process to determine the "effectiveness" of the labeling, written questionnaires were used in a non-aquatic setting and distributed to students and

others including a panel in New Jersey. No attempt was made to review the labeling in a live or personal watercraft setting. No attempt to gauge visibility of labeling on a PWC was attempted. No review of the questionnaire by outside reviewers included the question of appropriate location and conspicuity of the warnings to operators and passengers.

The general label on the Yamaha FRZ Waverunner is presented in reverse type, white on a black background. White on black is clearly not as fluent or easy to read and therefore easier to understand than the standard black text on white. It is placed directly under the handlebars and the operator directly blocks the view of the passengers. One cannot act on the content of a label if one cannot see it.

Yamaha claims in their Answers to Interrogatories that protective wear was available in 2009 and it was up to the consumer to make a choice to understand the danger and wear protective bottoms. The current Yamaha women's apparel offerings at www.shopYamaha.com provides a choice of three pairs of shorts for use on a Waverunner. Yet no place on that website does Yamaha identify the hazard or make any reference to the danger or provide any other warning that indicates why it is safety critical to wear those shorts. Two of the available shorts, one which sells for \$39.99, the other \$42.99, are actually neoprene sport shorts. The website says that the neoprene sport shorts are great for the beach and made from 2 millimeter neoprene. The features include:

- flat lock stitching
- super stretch side panels
- elastic drawstring waist
- comfort and flexibility

Nowhere does it indicate that they have any protective nature.

For \$64.49 the women's Yamaha ride shorts feature:

- Baja body
- Satin twill accent panel and black side panels ripstop
- 2 mm neoprene inner liner
- Tie in the front with zipper fly
- 5 inch hidden zipper pocket on the back right side
- Mesh pouch and key loop
- Sewn eyelets to outer shorts for drainage

Nothing indicates that wearing such shorts can substantially reduce the potential for injury from the jet thrust from the rear nozzle.

Analysis

- To substantially reduce or eliminate injury, a warning must provide a signal word to alert the user, provide adequate information to identify the hazard and its severity, indicate how to avoid it and the consequences of failing to avoid the hazard. It must be readable, understandable, and clearly conspicuous to the person who needs the information and motivate the user to protect themselves. This is most important when the severity of injury can be catastrophic, but the danger is otherwise latent or unknown to the user.
- In the case of the Yamaha FRZ Waverunner, the warnings are neither readable nor conspicuous to passengers who require the information to avoid the severe consequence of injury. Placed on the console under the handlebars, hidden between the legs of the operator, the safety information is not readily available to the passenger. She is deprived of the critical safety data she needs to protect herself from injury.

- Yamaha's labeling on the FRZ Waverunner fails to comply with the industry consensus ANSI Z535.4 Standard for Product Safety Signs and Labels as published by the American National Standards Institute.
- The ANSI standard requires a warning label to address both normal and reasonably foreseeable use and misuse, based on an understanding of how the product is used by operators and passengers.
 - 4.11.2.1 Permanent safety sign or label: Information affixed to a product to warn against potential exposure to hazards inherent in the normal use associated with the product, or which might be created during other reasonably anticipated product use or misuse. The sign or label is to be permanently affixed to the product so that it cannot be easily removed.
- The standard states that the Word Message should be concise and readily understood.
 - 6.5.1 Multiple messages: Multiple messages should be provided with sufficient space between them when feasible, to prevent them from visually blending together.
 - Section 9 of the ANSI Standard addresses sign and label placement.
 - 9.1 Location: Product safety signs and labels shall be placed such that they will: (1) be readily visible to the intended viewer and (2) alert the viewer to the potential hazard in time to take appropriate action.
- The label on the Yamaha FRZ Waverunner is clearly inadequate in its content and placement and creates an unreasonable risk of catastrophic injury, particularly to women, under foreseeable conditions well-known to Yamaha for nearly twenty (20) years.

As noted above, Paul Frantz of Applied Safety and Ergonomics, Inc. was a principal author of the industry funded personal watercraft (PWC) labeling study. In the case of <u>Colombo v. BRP</u>, two young women fell off the rear of a PWC and were severely injured vaginally and rectally. Commenting on the use of protective equipment by PWC passengers in the general population, Mr. Frantz stated:

As with PWC orifice injuries, for many of these products activities:

- There are multiple strategies that can be used to reduce the risk of injury
- There are recommendations to wear protective equipment
- The use of protective equipment is not widely considered necessary for reasonably safe participation in the activity
- The rate of use of recommended equipment can very widely from situation to situation
- The overall rate of equipment use may generally be considered low
- The rate of protective equipment usage does not, in and of itself, determine the risk of injury or the acceptability of the product or activity.

In the case of <u>Colombo v. BRP</u>, I developed a number of suggested warnings addressing the identical hazard associated with vaginal and rectal injuries from the thrust nozzle of a personal watercraft. Sample warnings from <u>Colombo</u> are attached and apply equally to the FRZ Waverunner.

In addition, a pictorial that shows a passenger being thrown off the back of a personal watercraft with the thrust from the rear impacting them can be added as I noted in my deposition in that case.

Yamaha clearly knew of the danger of the jet thrust causing devastating injury to young women from falling off the back of a Waverunner. They knew for 20 years before they produced the subject Yamaha FRZ Waverunner and sold it to Thomas Fimple. Yet Yamaha never placed a warning where it was visible to girls like Angela Ruggierio seated on the rear behind their boyfriend and other operators. Yamaha deprived Angela Ruggierio and others of the information they needed to protect herself. They still do.

Mm7 lutres December 7, 2015



- Severe injuries to passengers rectum and vagina from falling into the extremely high pressure water jet stream at the rear of the Sea-Doo.
- Always wear a wet suit bottom to protect your body.

 Denim and heavy shorts may provide some injury protection, but are not as effective in protecting sensitive body parts.

 A bathing suit will not protect you from injury.
- Always maintain a tight grip on the strap or person in front, especially during start up acceleration to avoid devastating injury to your genital areas.

DRAFT Sample Language WFK 11-30-11



- Severe injuries to passengers rectum and vagina from falling into the extremely high pressure water jet stream at the rear of the Sea-Doo.
- Passengers must always wear a wet suit bottom or heavy protective shorts.
 A bathing suit will not protect them from injury.
- Sudden acceleration can throw passengers into the water jet and cause catastrophic injury. Always increase throttle slowly with passengers on-board.

DRAFT Sample Language WFK 11-30-11 Compensation for research and analysis is \$1950 per 8 hour day. Fees for deposition and trial are \$2950 per day.

Materials Reviewed

Police Report

Plaintiff's Disclosure

Defendant's Disclosure

Plaintiff's Answers to Interrogatories and Response to Notice to Produce

Photographs

AtlantiCare chart

Defendant's Answers to Interrogatories

Depositions of: Angela Ruggierio

Thomas Fimple with Exhibits

Salvatore Chiaradonna

John Hopkins Ben Fisher Jason Klemm

YMUS 0001 to 0603

Video produced by Yamaha

"Vaginal Laceration following a Jet-Ski Accident," Journal of Obstetrics and Gynecology, 1991

"Rectal Injury caused by a Personal Watercraft Accident," Journal of Diseases of the Colon and Rectum, 1999

Development and Evaluation of Labeling for Personal Watercraft, Applied Safety and Ergonomics Inc., November 1999

www.shopYamaha.com

ANSI Z535.4 Standard for Product Safety Signs and Labels

Paul Frantz of Applied Safety and Economics Inc. Report in Colombo v. BRP